

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP.,
Plaintiff,

v.

BlueWillow Biologics, Inc.
ROBIN ROE 1 through 10, gender
neutral fictitious names, and ABC
CORPORATION 1 through 10 (fictitious
names).

Defendants.

CIVIL ACTION No. 4:21-cv-10312

Hon. F. Kay Behm

DECLARATION OF EDWARD A. LEMMO, Ph.D.

I, Edward A. Lemmo, being of full age, do hereby depose and say the following under pains and penalties of perjury under the laws of the United States and the State of Michigan:

1. I am a consumer healthcare corporate consultant. I earned a Ph.D. in nutrition science from Rutgers University in 1979. Since that time, I advised several pharmaceutical consumer healthcare companies and biomedical firms and evaluated their products. I served as a technical advisor for the development of dietary supplement products.

2. I earned a B.S. degree in chemistry from St. Francis College, Brooklyn, NY, and both an M.S. and Ph.D. in nutrition science in 1977 and 1979, respectively.
3. During my period of employment from 1978 until 2007, I was:
 - Clinical Trial Coordinator for Pharmacia Laboratories, Piscataway, NJ;
 - Director of Nutritional Technology for ICN Pharmaceuticals, Faraday Laboratories Division, Costa Mesa, CA;
 - Marketing Manager for Pall Biomedical Products, Glen Cove, NY;
 - Director of Nutritional Sciences for General Nutrition Centers, Inc., Pittsburgh, PA;
 - Vice President of Product Development for Solgar Vitamin and Herb Division of Wyeth Consumer Healthcare Products, Leonia and Madison, NJ; and
 - Vice President of Product Development for BioBalance Corporation, New York, NY.
4. As an independent consultant, I advised the following corporate clients:
 - American Vitamin, Ramsey, NJ;
 - Nutrmerica, Lincoln Park, NJ;
 - Nutrition 21, Purchase, NY;
 - IVC Industries, Freehold, NJ;
 - Church & Dwight, Princeton, NJ;
 - Matrixx Initiatives, Inc., Princeton, NJ;

5. My resume is attached to this declaration as Exhibit 1.
6. In 2019, I was engaged by Trutek Corp. (hereinafter, "Trutek") to serve as a technical expert in their patent infringement lawsuit against Matrixx Initiatives, Inc., litigated in the District of New Jersey.
7. In 2022, I was engaged by Plaintiff, Trutek Corp. to serve as a technical expert in the above captioned lawsuit against, Defendant BlueWillow Biologics, Inc. (hereinafter, "BlueWillow").
8. On June 27, August 15, and September 29, 2022, I prepared technical reports that were submitted to BlueWillow's counsel. Also, on September 24, 2022, I submitted a declaration to this court regarding construction of the asserted claims of the '802 Patent.
9. An essential property of the disclosure and claims for the method and formulations of the '802 Patent is the presence of a surface electrostatic charge that attracts harmful particles. In claims 6 and 7, benzalkonium chloride is used both as a cationic agent (to create a positive electrostatic charge) and as a biocide.
10. As of February 2021, BlueWillow was advertising its NanoBio Protect product on its website. On that website, BlueWillow stated:

"NanoBio Protect places the BZK¹ antiseptic on the surface of nano-droplets, which results in at least four key advantages:

- *The nano-droplets are attracted to germs by electro-kinetic charge and present the BZK in such a way to enable killing of germs on contact.*
- *The droplets persist on skin for 4 or more hours, enabling long-lasting effectiveness.*
- *The droplets significantly hydrate skin to avoid dryness and cracking that can allow germs in.*

¹ BZK is BlueWillow's acronym for benzalkonium chloride.

- *And lastly, when bound to nano-droplets, BZK is non-irritating to the skin.*

NanoBio Protect kills germs via membrane disruption. NanoBio Protect is comprised of positively charged droplets that are 300–600nm in size. The droplets are attracted to negatively charged germs in the skin. As shown to the right, the nano-droplets physically disrupt the outer membrane of germs, killing on contact."

A copy of the relevant portion of the BlueWillow website is attached hereto as Exhibit 2.

11. It is very important to ascertain whether Defendant BlueWillow's accused NanoBio Protect product produces an electrostatic charge when applied to a surface and whether the charge produced by that product is similar (in order of magnitude) to Trutek's NasalGuard products, which are protected by the '802 Patent.
12. I am familiar with Trutek's '802 Patent as well as Trutek's products derived from that patent. I am also familiar with nanotechnology and the effects of cationic agents in producing positively charged electrostatic fields. I am familiar with benzalkonium chloride, both as a cationic agent and as a biocide.
13. I have read and am familiar with the expert reports of Dr. Alexei Ermakov and Shane Burns that were submitted in this above captioned matter.
14. On Friday, October 7, 2022, I visited the laboratory of Dr. Alexei Ermakov at Rutgers University in Piscataway, New Jersey. On Monday, October 17, 2022, I visited the laboratories of Shane Burns at Electro-Tech Systems, Inc. in Perkasie, PA.

IN-PERSON SESSION WITH DR. ALEXEI ERMAKOV

15. Also present at my meeting with Dr. Ermakov was Ashok Wahi, Chief Science Officer of Trutek Corp., and Stanley H. Kremen, Esq., lead counsel in the above captioned matter.
16. Dr. Ermakov is an Assistant Professor and Director of Chemistry Instruments and Experiments at Rutgers University.
17. **In 2019**, Ashok Wahi approached Dr. Ermakov inquiring whether he could compare the surface electrostatic charges of various materials. In response, Dr. Ermakov developed an apparatus to perform such comparisons.
18. At that time, Dr. Ermakov used this apparatus to compare the surface charges of products on behalf of Trutek, which were the subject of another litigation.
19. Afterwards, Dr. Ermakov used this apparatus to compare the surface electrostatic charges of materials for other unrelated purposes..

DESCRIPTION AND OPERATION OF THE APPARATUS

20. The apparatus is mounted and contained within a metal box having a hinged lid that may be in the open or closed position. Inside the box, the apparatus consists of a small rotating turntable upon which a sample substrate is affixed. A sensing electrode is mounted above the substrate. The sensing electrode is approximately 10 mm in length. It is made of 1.3 mm diameter copper wire. When the box is closed, the sensing electrode rests approximately 1.5 mm above the surface of the substrate. The

sensing electrode is connected in series to a Keithley Instruments Nano-Volt Amplifier with a parallel capacitor and resistor, which in turn is connected to a volt meter. The output is displayed on an oscilloscope screen. The capacitance and resistance of the input circuitry of the amplifier are 80 pf and 50 MΩ, respectively.

21. The surface electrostatic charge is calculated using the well-known formula:

$$Q = V \cdot C / A$$

where: Q = charge per unit area,
 V = measured voltage on the sensing electrode,
 C = capacitance, and
 A = area of the sample under the sensing electrode.

22. The objective is for this apparatus to measure the surface electrostatic charge of a material applied to a substrate, but independently of the substrate itself. To accomplish this, only half of sample substrate is coated with the material, and the other half is uncoated. The substrate is then affixed to the turntable. As the substrate rotates underneath the sensing electrode, the apparatus measures the surface charge of the coated substrate for one half of the time, and measures the surface charge of the uncoated substrate for the other half of the time. Since only one substrate is used for each measurement, the effect of the surface charge of the uncoated substrate could be eliminated. Thus, the measurement of surface electrostatic charge for any material coating is substrate independent. The apparatus is self-calibrating.

USE OF THE APPARATUS IN THE PRESENT LAWSUIT

23. According to Dr. Ermakov, in early 2021, he was asked by Mr. Wahi to compare the surface electrostatic charges of several different samples that were presented to him by Trutek personnel. According to Mr. Wahi, the samples submitted to him for comparison were BlueWillow's NanoBio Protect solution, Trutek's NasalGuard Airborne Particle Blocker (Gel), and Trutek's NasalGuard Misting Spray (Nasal Spray). The samples presented to Dr. Ermakov were prepared in vials by Trutek personnel. Other than the vials having labels that differentiated the samples, Dr. Ermakov was unaware of the specific materials presented to him for measurement.
24. Dr. Ermakov used printer paper as the substrate because any material thicker than paper would inhibit movement of the turntable. As a control sample, he used a blank uncoated piece of paper. In this way, the surface electrostatic charge of the substrate itself would be known. According to Dr. Ermakov, the one gel sample was applied uniformly to the paper using a swab. The liquid samples were applied either by spray or by using a swab and were allowed to dry. No particular care was taken to determine how much of each sample was applied to each substrate.
25. In my opinion, concern over the amount of each sample applied to the substrate is unnecessary. In actual use, the NasalGuard gel is applied to the nasal passages by smearing it with a fingertip, and the liquids are either sprayed or swabbed. Thus, simulation of actual application to

human tissue is impractical. The products are effective in actual use because they have electrostatic charges. Neither the Trutek products nor the BlueWillow product is a pharmaceutical. Their effects take place outside rather than inside the body. Their objective is to catch, hold, and kill harmful germs prior to being inhaled into the respiratory system. It is more like a cosmetic. Its action is very much like a mask, which acts as a barrier with electrostatic charge that attracts germs. Thus, concern over the amount of material applied to the substrate is irrelevant. The objective of the test is merely to determine whether a surface electrostatic charge is generated by the BlueWillow product and whether its charge is similar to that of the Trutek product.

26. Further, while attempts were made to ensure that the coating on a substrate was uniform, because the substrate was spinning, the results obtained represented an average over the entire coated substrate.
27. In addition, while the magnitude of surface electrostatic charge might be affected by temperature changes over a wide range, the difference between room temperature and body temperature is not great enough to have a significant effect on the charge. Also, the emphasis of the experiment was not to determine the surface electrostatic charge accurately across multiple environmental conditions. It was merely to ascertain whether the various products exhibited comparable electrostatic charges of similar magnitude.

28. Dr. Ermakov noted in his report that 1) the test products, *i.e.*, NasalGuard Airborne Particle Blocker gel, NasalGuard Misting Spray, and NanoBio Protect solution all demonstrated the presence of a surface electrostatic charge; and (2) the surface electrostatic charge measured was determined to be approximately (in order of magnitude) similar in all three product samples tested.
29. Dr. Ermakov demonstrated the apparatus to me, and its operation was entirely straightforward and easy to understand. The oscilloscope output was easy to read.
30. In his position at Rutgers University, Dr. Ermakov regularly designs instrumentation for chemical experimentation. Although Dr. Ermakov designed his apparatus to solve the specific problem of measuring the surface electrostatic charge of a chemical applied to a substrate independent of the substrate used, his solution to the problem followed logical principles. Its design and operation can be easily understood by virtually any undergraduate physics student. It is the natural solution to this type of problem. It is not rocket science.

IN PERSON SESSION WITH SHANE BURNS

31. Also present at my meeting with Shane Burns was Ashok Wahi, Troy Anthony, and Stanley H. Kremen, Esq. Mr. Burns and Mr. Anthony are employees of Electro-Tech Systems, Inc. (hereinafter, "ETS"). The testing by Mr. Burns was reviewed by Mr. Anthony.

32. In performing his test, Mr. Burns used a coulombmeter in combination with a Faraday Cup (or a metal probe) for making charge measurements. A nanocoulombmeter is a coulombmeter that is capable of measuring electrostatic charge down to the accuracy of a nanocoulomb. This is a standard method of conducting this type of experiment. Electrostatic charge on an object can be measured by placing it inside a Faraday Cup. The charge is transferred to the cup and displayed on the meter's display. The Faraday Cup of the Coulombmeter has an outer, grounded metal shield that surrounds an inner electrode. The inner electrode, which is electrically isolated from the shield, is connected to a meter to measure the charge. The coulombmeter allows the electrostatic buildup to be easily measured simply by applying the instrument's probe to its lead. The Faraday Cup is a metal (conductive) cup designed to catch charged particles in a vacuum. The resulting current can be measured and used to determine the number of ions or electrons hitting the cup.
33. The test standard followed by Mr. Burns was ANSI/ESD ADV11.2. Measurement of electrostatic charge using a Faraday Cup and coulombmeter has been a standard measurement technique for more than a century. A good description of the process is available in Cameron, D.S., "Chemistry, Electrochemistry, and Electrochemical Applications | Silver Coulometer," Encyclopedia of Electrochemical Power Sources, 2009 (available from Science Direct (www.sciencedirect.com)).

34. The test equipment used by Mr. Burns was the ETS Model 230 Nanocoulomb meter with a Faraday Cup. The Model 230 measures electrostatic directly, displaying the result in nanocoulombs. The evaluation of electrostatic charge is performed by measuring the amount of charge developed on a material. When used with a suitable Faraday Cup, the charge on a wide range of material types and sizes can be measured accurately by the Model 230 Nanocoulomb Meter. The Model 230 meets the requirements for charge measurement as specified in applicable ESDA, ASTM, EIA, DOD, as well as many other industry standards. The Model 230 is a complete instrument for measuring charge directly in nanocoulombs. This instrument may be used with a Faraday cup or pail or a detector probe. It can be used alone to measure charge on capacitors or from capacitive discharge systems (with adequate protection).
35. Mr. Burns conducted his study to determine whether Trutek's NasalGuard Misting (Nasal Spray) had a similar charge to BlueWillow's NanoBio Protect product. Pigskin was used as the substrate for testing the products. Pigskin is often used as a testing model for human skin. "The skin of pigs is composed of an epidermis and dermis with characteristics like those of human skin. The regeneration time of epidermal cells is 30 d for pig compared with 27 to 28 d for human."² The pigskin was deionized

² Yu Liu, Jun-ying Chen, Hai-tao Shang, Chang-e Liu, Yong Wang, Rong Niu, Jun Wu, Hong Wei, "Light Microscopic, electron Microscopic, and Immunohistochemical Comparison of Bama Minipig (*Sus scrofa domestica*) and Human Skin," *Comp Med* 2010 Apr. (60(2); 142-148. Published online 2010 Apr., PMID: 20412690 | PMCID: PMC2855042


repeatedly with Simco Model AerostatXC to neutralize existing charge and measured repeatedly to see how much the substrate material would affect the result. The substrates were coated with the sample solutions using a cotton swab with approximately 1.5 ml for a smooth and uniform application. The samples were air dried, and the measurements were performed.

36. The results of the Burns study demonstrated the presence of a surface electrostatic charge of similar order of magnitude between the NasalGuard Misting Spray of Trutek and the BlueWillow NanoBio Protect solution.

GENERAL STATEMENT

37. The preceding statements made by me are true to the best of my knowledge and belief.

I make this declaration and the statements herein under pains and penalties of perjury under the laws of the United States and the State of Michigan.


Edward A. Lemmo

Dated: May 18, 2022

EXHIBIT 1

Edward A. Lemmo, Ph.D.
60 Gilroy Street
Staten Island, New York 10309
(917) 837-1470
Email: edlemmo@gmail.com

EDUCATION

Ph.D. Nutrition Science, Rutgers University, New Brunswick, NJ (1979)
M.S. Nutrition Science, Rutgers University, New Brunswick, NJ (1977)
B.S. Chemistry, St. Francis College, Brooklyn, NY (1973)

EXECUTIVE TRAINING COURSES

Executive Leadership Program, Princeton, NJ
Time Management Skills, Teaneck, NJ
Media Communication Skills, New York City, NY

EMPLOYMENT EXPERIENCE

2007-Present **Consumer Healthcare Corporate Consultant**
Self-employed Consultant - Consumer Healthcare

2005-2007 **BioBalance Corporation**, New York, NY
Vice President, Product Development

Person primarily responsible for investigating its probiotic product PROBACTRIX™ to be used for treating pouchitis and other gastrointestinal disorders. Probiotic products are an optional alternative to the probiotic Lactobacillus acidophilus. In charge of all scientific product evaluation conducted at company headquarters.

1999-2005 **Wyeth Consumer Healthcare**, Leonia and Madison, NJ
Vice President, Product Development

Division of American Home Products
Formerly Whitehall-Robbins Consumer Healthcare

Managed product development for SOLGAR®, and contributed towards CENTRUM®, and CALTRATE®, brands. Responsible role in scientific affairs and new business

development opportunities. Further, responsible for evaluation of acquisition of new business entities.

1992-1999

General Nutrition Centers, Inc., Pittsburg, PA
Director, Nutritional Sciences

Analyzed safety of amino acid products for presentation to the FDA and FTC and other U.S. government agencies. Evaluated and made recommendations regarding nutritional and homeopathic products. Performed quality assurance activities related to label claims and product safety. Responsible for introduction of the new PRO-PERFORMANCE sports nutrition product line into the GNC retail marketplace.

In 1993, for Quigley Corporation, I evaluated the safety and efficacy of Cold-EEZE[®] zinc lozenges to be used to shorten a common cold as a possible line of homeopathic products exclusively marketed by GNC.

1989-1992

Pall Biomedical Products, Glen Cove, NY
Marketing Manager

Responsible for marketing activities of Intravenous filtration devices, and Heat and Moisture exchange respiratory products. Wrote all scientific evaluation documents related to Heat and Moisture Exchange respiratory product for presentation to anesthesiologists regarding prevention of injury from patients breathing cold dry gas during surgery. Developed scientific presentations, videos, and product marketing material for use by healthcare professionals.

1984-1989

ICN Pharmaceuticals, Costa Mesa, CA
Director of Nutritional Technology

Faraday Laboratories Division

Product development of nutritional supplements for use by chiropractic and alternative health practitioners throughout the United States and Canada. Product brands included Nutridyn[®] and Sivad Bioresearch[®]. Responsible for new product development, wrote technical literature, and prepared and delivered scientific educational presentations to practitioners at chiropractic colleges and chiropractic meetings.

1976-1977

**Pharmacia Laboratories, Piscataway, NJ
Clinical Trials Coordinator**

Assisted veterinarian in analysis of equine blood samples. Performed evaluation analysis of HEALON[®] products comprising hyaluronic acid, and their effect on tissues.

CORPORATE CONSULTING EXPERIENCE

2011

**Matrixx Initiatives, Inc., Princeton, NJ
Scientific Affairs Consultant**

Performed research associated with ZICAM[®] oral zinc product. Provided guidance for coordinating research trials. Managed human efficacy clinical trials.

1998-1999

**Church & Dwight, Princeton, NJ
Scientific Advisor**

Evaluated consumer healthcare products. Explored and determined market for magnesium based organo-metallic agents for use in dietary supplements.

1998-1999

IVC Industries, Freehold, NJ

IVC is a contract manufacturer of generic vitamins. Responsible for new product development. Assisted the marketing staff with product label claims.

1996

Nutrition 21, Purchase, NY

Company is a supplier to GNC. Performed consulting work regarding their products.

1996

Nutramerica, Lincoln Park, NJ

Technical advisor for the development of a dietary supplement product line.

CORPORATE CONSULTING EXPERIENCE (continued)

1996 **American Vitamin, Ramsey, NJ**

Company is a contract manufacturer. Performed new product development and assistance with evaluation of raw materials from India.

COLLEGE TEACHING EXPERIENCE

2013-2018 **Touro College, New York City, NY**

Taught in nursing school. Courses included pathophysiology, genetics, anatomy and physiology and tutored microbiology

2008-2014 **University of Medicine & Dentistry of New Jersey (UMDNJ), Newark, NJ**

Taught in nutrition program. Courses included general chemistry, anatomy and physiology, biochemistry, and microbiology.

1977 and **New York University, New York, NY**

2000-2003 Taught in graduate nutrition program, vitamin and mineral metabolism

2011-2012 **Cedar Crest College, Allentown, PA**

Taught courses in nutritional biochemistry and metabolism.

1984-1989 **University of New Haven, West Haven, CT**

Taught graduate level course in vitamin and mineral nutrition.

1974-1984 **Brooklyn College, CUNY, Brooklyn, NY**
Assistant Professor

Taught nutrition courses to pre-medical and nutrition students.

1973-1977 **Rutgers University, Piscataway, NJ**

Taught general biology lab and mineral metabolism.

EXHIBIT 2



Bringing Nanoscience to Life

Company ▼ NanoBio® Protect NanoVax® Platform ▼ News ▼

NanoBio® Protect Nasal Antiseptic Solution



NanoBio[®] Protect

NanoBio® Protect is an alcohol-free nasal antiseptic solution that can be used to help reduce germs on skin that can cause infections. The product is easy to apply with any cotton swab for use on the skin around the rim of your nose as well as the skin up to one-half inch inside each nostril. It is non-irritating, fragrance-free and leaves no residue after application.

NanoBio® Protect is an FDA regulated over-the-counter skin antiseptic that incorporates the active ingredient benzalkonium chloride (BZK), which has been used in humans as a topical skin antiseptic since the 1940's. NanoBio®

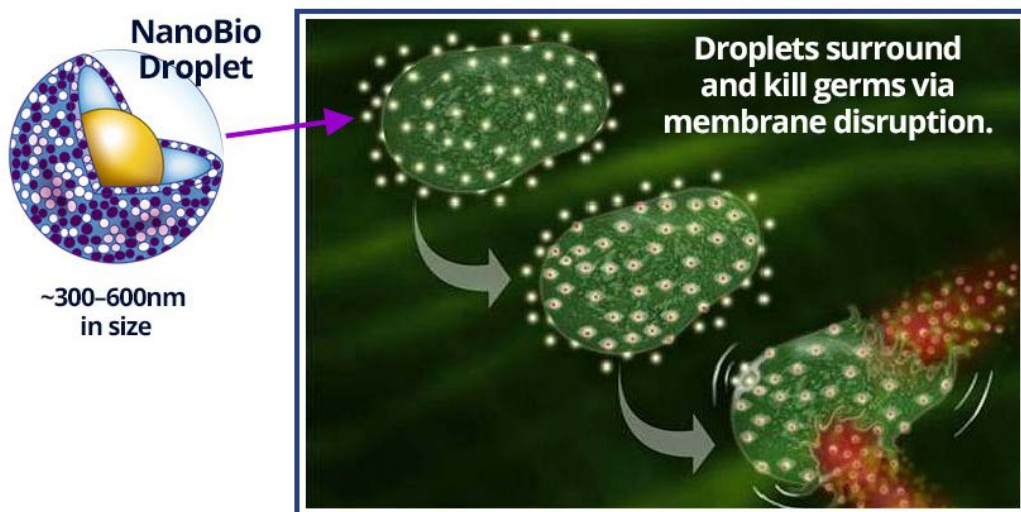
Protect is similar in concept to a hand sanitizer but is designed for use on the skin inside and around the nose where germs frequently enter the body.



The unique effectiveness of NanoBio® Protect is derived from BlueWillow's patented nanotechnology. NanoBio® Protect places the BZK antiseptic on the surface of nano-droplets, which results in at least four key advantages:

1. The nano-droplets are attracted to germs by electro-kinetic charge and present the BZK in such a way to enable killing of germs on contact,
2. The droplets persist on skin for 4 or more hours, enabling long-lasting effectiveness,
3. The droplets significantly hydrate skin to avoid dryness and cracking that can allow germs in.
4. And lastly, when bound to nano-droplets, BZK is non-irritating to the skin.

NanoBio® Protect kills germs via membrane disruption. NanoBio® Protect is comprised of positively charged droplets that are 300–600nm in size. The droplets are attracted to negatively charged germs in the skin. As shown to the right, the nano-droplets physically disrupt the outer membrane of germs, killing on contact.



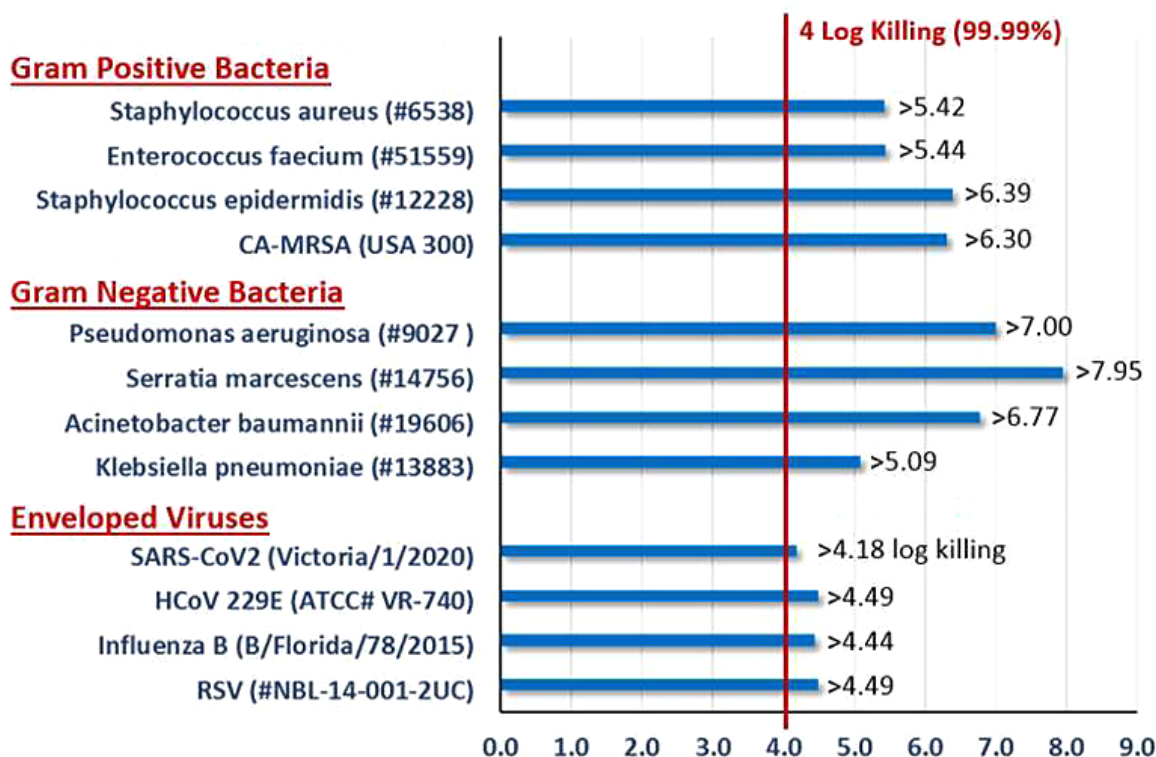
NanoBio® Protect is applied by thoroughly swabbing the skin up to one-half inch inside of each nostril and is recommended for use to help reduce germs on the skin in and around the nose that can cause infections. It should be used in conjunction with frequent handwashing, limited touching of the face, and social distancing to help minimize infection. Each 0.75 oz bottle of NanoBio® Protect will provide 40 or more treatments. A single application should involve the use of two swabs, including one for each nostril, or the use of a double-sided swab.

The product can be applied to the skin every 4–8 hours as needed, and is recommended for use during periods of increased risk of exposure to germs. For example, a healthcare worker might apply NanoBio® Protect two or more times a day. A flight attendant might apply the product 1–2 times during a long flight. Whereas, someone that is mostly staying at home in isolation may only need to apply it once a day or every few days prior to heading to the store or to an appointment.

Scientific Research Behind NanoBio® Protect

BlueWillow's
nasal
antiseptic

has not
been
clinically
tested to
confirm
protection
against
COVID-19
infection in
humans. It
has



demonstrated both anti-bacterial and anti-viral activity in laboratory tests making it a potentially important additive measure to reduce the risk of infection

Standard *in vitro* lab experiments demonstrate that NanoBio® Protect kills more than 99.99% of germs within 60 seconds of exposure, as shown in the graph to the right.

Recent studies conducted by Public Health England also demonstrate NanoBio® Protect's ability to kill COVID-19 virus in laboratory tests. However, as stated above, studies to test for protection in humans have not yet been performed.

In addition, *ex vivo* tests in human skin (Figure A below) demonstrate that NanoBio® Protect persists on skin up to 7x better than commercial products and aqueous solutions containing the same BZK antiseptic agent. In vivo studies conducted in human volunteers (Figure B below) demonstrate that a single application of NanoBio® Protect significantly increases skin hydration for at least 3 hours, as compared to common hand sanitizer products: